SEP 2 4 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010893

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: March 23, 2001

Name of Device and Name/Address of Sponsor

Name of Device
Hybrid Capture® 2 GC-ID DNA Test

Sponsor
Digene Corporation
1201 Clopper Road
Gaithersburg, MD 20878
Phone: (301) 944-7092
Facsimile: (301) 944-7091 / 240-632-7492

Common or Usual Name

HC2 GC-ID DNA Test

Classification Name

Neisseria - LSL

Predicate Device(s)

Digene Hybrid Capture® II GC-ID DNA Test cleared under K981485 on November 29, 1999.

Device Description

The Hybrid Capture® 2 (HC2) GC-ID DNA Test is an *In Vitro* nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of Neisseria gonorrhoeae (GC) DNA in cervical specimens collected with the Cervical Sampler™ (Cervical Brush and Specimen Transport Medium™[STM]) and the Female Swab Specimen Collection Kit (Dacron Swab and Specimen Transport Medium). The HC2 GC-ID DNA Test is indicated for use with symptomatic or asymptomatic women as evidence of infection with *Neisseria gonorrhoeae.*

The HC2 GC-ID DNA Test may be used as a stand-alone test or may be used as a supplemental test to the HC2 CT/GC DNA Test for differentiation of *Neisseria gonorrhoeae* in specimens that are positive by the HC2 CT/GC DNA Test.

Specimens potentially containing *N. gonorrhoeae* DNA are denatured and then hybridized with a specific RNA probe cocktail. This cocktail contains a probe mixture chosen to minimize or eliminate cross-reactivity with DNA sequences from human cells, other bacterial species, *Neisseria* species other than *gonorrhoeae* or sequences from other microorganisms common in urogenital specimens. The GC probe cocktail supplied with the HC2 GC-ID DNA Test is complementary to approximately 13,800 base pairs or 0.7% of the *N. gonorrhoeae* genome (1.9 x 10^6 base pairs)[1].

The RNA:DNA hybrids resulting from hybridization are immobilized (captured) on the surface of a microplate-well, which has been coated with antibodies specific for RNA:DNA hybrids. The antibodies on the well surface capture the RNA:DNA hybrids. The immobilized hybrids are then reacted with alkaline phosphatase-conjugated antibody and a chemiluminescent substrate. As the substrate is cleaved by the bound alkaline phosphatase, photons are emitted and measured as Relative Light Units (RLUs) using a standard, FDA-cleared luminometer. Increased photon emission, resulting in an amplified signal, is achieved by conjugating multiple alkaline phosphatase molecules to each antibody molecule. Multiple antibodies bind to each RNA:DNA hybrid, further amplifying the signal.

The HC2 GC-ID DNA Test provides an RLU measurement that is qualitatively interpreted. This conversion calculation and report of the result is performed by the Digene DML 2000 Microplate Luminometer software.

The Rapid Capture System™ (RCS), a general laboratory use robotic pipetting and reagent handling system, was adapted for use with the Hybrid Capture CT/GC DNA Test for high volume sample-throughput testing. The instrument application that enables the RCS to be used with the HC2 CT/GC DNA Test did not require altering the basic fundamental operating principle of the manual assay in any way. The performance of the test when using the RCS application remains unchanged compared to the manual method of the HC2 GC-ID DNA Test.
To accomplish this degree of semi-automation with the assay, the following six procedural steps of the manual method are performed by the RCS on the instrument platform:

1. Specimen Pipeting
2. Reagent Dispensing
3. Microplate Handling
4. Microplate Mixing
5. Microplate Incubation
6. Microplate Washing

Denaturation of the cervical specimen in preparation for testing is performed offline in the primary collection tube, as done for the cleared manual method of the CT/GC DNA Test, prior to placing on the RCS platform. In addition, chemiluminescent signal detection and result reporting are performed using the offline luminometer system (Digene DML 2000 and the Hybrid Capture System Software) that functions in an equivalent manner to that currently cleared with the manual assays.

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[1] Kingsbury DT. Estimate of the genome size of various microorganisms. J Bacteriol 1969 Jun; 98(3) : 1400-1.

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Intended Use

The Hybrid Capture® 2 (HC2) GC-ID DNA Test is an *In Vitro* nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of Neisseria gonorrhoeae (GC) DNA in cervical specimens collected with the Cervical Sampler™ (Cervical Brush and Specimen Transport Medium™[STM]) and the Female Swab Specimen Collection Kit (Dacron Swab and Specimen Transport Medium). The HC2 GC-ID DNA Test is indicated for use with symptomatic or asymptomatic women as evidence of infection with *Neisseria gonorrhoeae.*

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Substantial Equivalence

The HC2 GC-ID DNA Test when using the Rapid Capture System Application is substantially equivalent to the HC2 GC-ID DNA Test when using the manual method as determined according to the Quality System Regulation (21 CFR 820). The testing completed under design control requirements demonstrated an agreement greater than 98 % between the manual and the RCS methods for the GC-ID DNA Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 2001

Mr. Mark A. Del Vecchio
Director, Regulatory and Clinical Affairs
Digene Corporation
1201 Clopper Road
Gaithersburg, MD 20878

Re: K010893
Trade/Device Name: Hybrid Capture® 2 GC-ID DNA Test
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. Direct serological test reagents
Regulatory Class: II
Product Code: LSL
Dated: August 22, 2001
Received: August 23, 2001

Dear Mr. Del Vecchio:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K010893

Device Name *Hybrid Capture 2 GC-ID DNA Test*

Indications for Use

The Hybrid Capture® 2 (HC2) GC-ID DNA Test is an *In Vitro* nucleic acid hybridization assay with signal amplification using microplate chemiluminescence for the qualitative detection of Neisseria gonorrhoeae (GC) DNA in cervical specimens collected with the Cervical Sampler™ (Cervical Brush and Specimen Transport Medium™[STM]) and the Female Swab Specimen Collection Kit (Dacron Swab and Specimen Transport Medium). The HC2 GC-ID DNA Test is indicated for use with symptomatic or asymptomatic women as evidence of infection with *Neisseria gonorrhoeae.*

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Lee L. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010893

Prescription Use ✓
(Per 21 CFR 801. 109)

Over-The-Counter Use_____